IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

MONISHA SHANNON,

Plaintiff,

-vs-

JOHNSON & JOHNSON, et al.,

Defendant.

Case No. 1:09 oe 40043

MEMORANDUM OPINION

KATZ, J.

This matter is before the Court on Defendants' motion for summary judgment, Plaintiff's opposition and Defendants' reply thereto. This Court has jurisdiction pursuant to 28 U.S.C. § 1332. For the reasons that follow, Defendants' motion for summary judgment is granted in part and denied in part.

I. BRIEF BACKGROUND

This case is one of many to arise out of the litigation involving the Ortho Evra® birth control patch. In March 2006, the Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, centralized all civil litigation in the Northern District of Ohio, noting the following common allegations:

> i) the Ortho Evra contraceptive patch was defectively designed, and ii) plaintiffs received inadequate warnings regarding Ortho Evra's side effects and safety profile. All actions seek damages for personal injury and/or economic damages on behalf of users of Ortho Evra, asserting various state law claims, such as negligence, products liability, breach of warranties, and negligent and/or fraudulent misrepresentation regarding the risks of using Ortho Evra.

In re Ortho Evra Products Liability Litigation, 1:06 cv 40000, MDL 1742 (N.D. Ohio) (Doc. No. 1).

In the present complaint, Monisha Shannon ("Shannon" or "Plaintiff"), a Michigan resident, alleges use of the Ortho Evra® patch from March 2003 until June 2003. The patch was prescribed by her physician in Michigan. Ms. Shannon suffered a pulmonary embolism event in June 2003, in Michigan. She filed this action in June 2009 in the District of Minnesota against Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson ("Defendants") alleging the following causes of action: (1) failure to warn; (2) breach of express and implied warranties; (3) negligence; (4) fraud, misrepresentation, suppression and concealment; (5) wantonness; (6) violation of Minnesota statute § 325F.67-False Advertising Act; (7) violation of Minnesota statute § 325F.69-Consumer Fraud Act; and (8) violation of Minnesota statutes § 325D.13 & 325D.44–Unlawful and Deceptive Trade Practices Acts.

II. MOTION FOR SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). The moving party bears the initial responsibility of "informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553, 91 L. Ed. 2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant's claim. *Id.* at 323-25. Once the movant meets this burden, the

opposing party "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250, 106 S. Ct. 2505, 2541, 91 L. Ed. 2d 202 (1986) (*quoting* FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient "simply [to] show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986). Rather, Rule 56(e) "requires the nonmoving party to go beyond the pleadings" and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324, 106 S. Ct. at 2553; *see also Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322, 106 S. Ct. at 2552.

"In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party." *Williams v. Belknap*, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, "'at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter,'" *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, "[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact." *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment "is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried." *Abercrombie & Fitch*

Stores, Inc. v. Am. Eagle Outfitters, Inc., 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately, this Court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

III. Discussion

Defendants contend Plaintiff does not have a cause of action under Michigan law absent a federal finding of fraud or bribery of the Food and Drug Administration. Plaintiff disputes this assertion and contends Defendants' summary judgment motion does not address the claims brought pursuant to the Minnesota statutes. It appears that both sides are in agreement that the non-Minnesota claims are governed by Michigan law, so the Court will first address those claims challenged therein brought under Michigan law.

A. Claims Brought Under Michigan State Law.

Defendants contend that Michigan's statute precludes a product liability action where the drug was approved by the Food and Drug Administration ("FDA") absent fraud or bribery on the FDA. The relevant Michigan statute reads in pertinent part:

> (5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of the order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is

> required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Mich. Comp. Laws § 600.2946 (1996).

In *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit addressed the issues of preemption and constitutionality as applied to exceptions (a) and (b) in the Michigan statute. In addressing preemption, the panel in *Garcia* considered the decision in *Buckman Co. v. Pls' Legal Comm.*, 531 U.S. 341 (2001), noting:

> As the district court properly found, "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims."

Id. at 966, quoting *Garcia v. Wyeth-Ayerst Labs.*, 265 F.Supp.2d 825 (E.D. Mich. 2003). The appellate panel found preemption deemed "§600.2946(5)(a) and (b) [] unconstitutional in some settings–including plaintiff's own suit (as she alleged bribery and fraud on the FDA but did not offer any federal findings) . . ." *Id.* However, the panel upheld the rest of the statute as valid under Michigan's general severability clause.

Plaintiff urges the Court to adopt the interpretation by the Second Circuit in *Desiano v. Warner-Lambert Co.*, 467 F.3d 86 (2nd Cir. 2007). The panel in *Desiano* considered the exemptions in §600.2946(5) but disagreed with the approach by the Sixth Circuit in *Garcia* and did not find preemption. Additionally, Plaintiff submits that the recent Supreme Court's

pronouncement in *Wyeth v. Levine*, 555 U.S. 555 (2009), alters the interpretation under *Garcia*. A brief review of the relevant Supreme Court decisions illuminates the discussion.

In *Buckman* the Court considered claims against a consultant who assisted a manufacturer of bone screws in navigating the regulatory process for drug approval. The application requested use for a particular purpose but once approved, the device was utilized for a different use. The claims alleged fraud on the FDA. The Court noted that there was not a presumption against preemption because the Medical Device Act and FDA, both federal schemes, were at issue and conflicted with state law fraud claims. Because the application was subject to the federal regulatory process, the claims arising out of that process were distinct from claims based on traditional state tort principles. Thus, the existence of federal enactments which were critical to a fraud-on-the-FDA approach, supported implied preemption of these claims.

In *Wyeth v. Levine*, a plaintiff brought failure-to-warn claims related to method of administration of the drug Phenergan, which she claimed resulted in amputation of her arm. Following a plaintiff's verdict in state court, the manufacturer sought review on the issue of preemption. In ascertaining the purpose of Congress, the Court looked to the history of the federal regulations regarding label changes and construed amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA") as imparting responsibility upon the manufacturer to update changes to their labels. Next, the majority noted Congress created the FDCA to "bolster consumer protection against harmful products," which did not include a remedy for those injured by the product because avenues of recovery were available via state court remedies. 129 S.Ct. at 1200. Finally, the Court held that it was Congress's intent and not the FDA's position statement which was relevant to a preemption analysis. On this basis, it was not impossible for Wyeth to comply with

both state and federal law; therefore, the Court found the state law failure-to-warn claims were not preempted by federal law.

The Plaintiff contends that the drug and FDA approval in both *Garcia* and *Wyeth* are indistinguishable, therefore, the determination in *Wyeth* prevails and allows her failure-to-warn claims to proceed forward. Moreover, she argues *Wyeth* undermines *Garcia* and requires application of the Second Circuit's decision in *Desiano*. This Court disagrees.

Both *Garcia* and *Wyeth* involved drug and FDA approval but unlike the state of Vermont, the Michigan legislature enacted a provision providing immunity to drug manufacturers absent two specific exceptions. In *Wyeth*, no such immunity provision was at issue. *Garcia* considered the provision precluding product liability suits and the exceptions therein and it remains valid precedent in the Sixth Circuit. *In re Aredia and Zometa Products Liability Litigation*, 352 Fed. Appx. 994 (6th Cir. 2009)(noting the Sixth Circuit's binding precedent under *Garcia*). Although the decision in *Desiano* was affirmed by an equally divided Court, *Warner-Lambert v. Kent*, 128 S.Ct. 1168 (2008), it carries no precedential weight. *Neil v. Biggers*, 409 U.S. 188, 192 (1972). *See also, In re Trasylol Products Liability Litigation*, __F.Supp.2d __, 2010 WL 5579867 **7-11 (S.D. Fla. 2010) (finding the rationale in *Garcia* more persuasive than *Desiano* in sustaining a motion in limine regarding the introduction of evidence the drug manufacturer provided incomplete or inadequate information to the FDA).

Under Michigan law, the definition of a product liability action is "an action based on a legal or equitable theory of liability brought for the death of a person or for an injury to a person or damage to property caused by or resulting from the production of a product." Mich. Comp. Laws § 600.2945(h). The term "production" is further defined as "manufacturing, construction,

design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instruction, marketing, selling, advertising, packaging or labeling." *Id*. at §600.2945(i). Plaintiff's remaining claims which are outside the preempted exceptions fall within this definition and constitute a product liability action under the terms of the statute. The Michigan Supreme Court in *Taylor v. Smithkline Beecham Corp.*, 468 Mich. 1, 658 N.W.2d 127 (Mich. 2003), upheld § 600.2946(5) as a proper legislative determination, noting that where "the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Id*. at 7, 658 N.W.2d at 131. As such, they are precluded as a matter of law. *White v. SmithKline Beecham Corp.*, 538 F.Supp.2d 1023 (W.D. Mich. 2008); *Zammit v. Shire US, Inc.*, 415 F.Supp.2d 760 (E.D. Mich. 2006); *Attorney General v. Merck Sharp & Dohme Corp.*, __N.W.2d__ 2011 WL 921669 (Mich. App. March 17, 2011).

Considering Plaintiff's claims in the context of the Michigan statute and there being no dispute that Ortho Evra® was subject to and successfully completed the FDA approval process[1], Plaintiff's product liability claims, as contained in Counts I through V, are precluded as a matter of law.

B. Claims Under the Minnesota Statute.

The claims enumerated in Counts VI through VIII are brought pursuant to Minnesota's consumer protection statutes. While the Defendants dispute the viability of the remaining claims,

[1] See Complaint at ¶ 32 and Answer at ¶ 32 indicating the FDA approved Ortho Evra® as a prescription drug on November 20, 2001.

the focus of the briefing and oral arguments focused on the Michigan statute. Therefore, at this juncture, the Court will deny the motion as to these claims.

IV. CONCLUSION

For the reasons stated above, Defendants' motion for summary judgment (Doc. No. 13) is granted as to Counts I though V and denied, without prejudice, as to Counts VI through VIII.

IT IS SO ORDERED.

S/ *David A. Katz*
DAVID A. KATZ
U. S. DISTRICT JUDGE